UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:

The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.
Case No. 1:18-op-45090 (N.D. Ohio)

The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al.
Case No. 1:17-op-45004 (N.D. Ohio)

MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster

MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT ON PREEMPTION BY PHARMACY DEFENDANTS, ABDC, CARDINAL, AND MCKESSON

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The federal Controlled Substances Act preempts the claims asserted by Plaintiffs against Pharmacy and Distributor Defendants.[1] State tort liability is preempted when it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona v. United States*, 567 U.S. 387, 399–400 (2012). Congress struck a balance between the risk of diversion and the risk of unavailability of important medications and vested DEA with the authority to implement that framework. The imposition of state tort liability would stand as an obstacle to DEA's ability to regulate and enforce that balance, would frustrate Congress's purpose, and is thus preempted.

I. Congress Struck a Balance in Enacting the Controlled Substances Act.

The availability of opioids presents a difficult policy question. In the Controlled Substances Act, 21 U.S.C. § 801, *et seq.*, Congress addressed two concerns. Many regulated drugs "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. § 801(1). But "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people." 21 U.S.C. § 801(2).

Congress thus enacted the Controlled Substances Act to "control the supply and demand of controlled substances," *Gonzalez v. Raich*, 545 U.S. 1, 19 (2005), which requires a regulatory balance. If the distribution of drugs is too restricted, then the American people will be deprived of drugs "necessary to maintain [their] health and general welfare." 21 U.S.C. § 801(1). If distribution of drugs is too free, then their improper use will have a "detrimental effect on the

[1] "Pharmacy Defendants" are CVS Rx Services, Inc. and CVS Indiana, L.L.C. ("CVS Distributors"), Rite Aid of Maryland, Inc., d/b/a Mid-Atlantic Customer Support Center ("Rite Aid"), Walgreen Co. and Walgreen Eastern Co. ("Walgreens"), HBC Service Company, an unincorporated operating division of Giant Eagle, Inc. ("Giant Eagle"), Discount Drug Mart ("DDM"), and Walmart Inc. ("Walmart"). "Distributor Defendants" who join in this motion are AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation.

health and general welfare." 21 U.S.C. § 801(2). Congress vested the Drug Enforcement Administration with authority to promulgate regulations (through notice-and-comment rulemaking) and enforce the statute with both considerations in mind.

The regulatory scheme is thus designed to foster Congress's twin goals "to foster the beneficial use of those medications" and "to prevent their misuse[.]" *Raich*, 545 U.S. at 24. To be sure, DEA promulgates regulations to prevent diversion. But it "takes just as seriously its obligation to ensure that there is no interference with the dispensing of controlled substances to the American public in accordance with the sound judgment of their physicians." Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,719-20 (Sept. 6, 2006). To this end, the regulations specify that "substantial compliance . . . may be deemed sufficient," vesting DEA with discretion in enforcing the regulatory scheme. 21 C.F.R. § 1301.71(b). Similarly, Congress directed that when determining whether to terminate a registration to distribute controlled substances, the Attorney General must balance "maintenance of effective control against diversion" with "other factors as may be relevant to and consistent with the public health and safety." 21 U.S.C. § 823(b); *see also* 21 U.S.C. § 824(a)(4) (revocation).

Deposition testimony confirms these dual duties. For example, Kyle Wright, a former DEA employee, testified that DEA has "a statutory obligation" to "make sure . . . there's a legitimate supply and that supply is protected." Wright Dep. at 240:2-16, Ex. A. Similarly, Demetra Ashley confirmed, "based on [her] 35 years of experience at DEA," that "what the office of diversion control is attempting to do is on one hand minimize the amount of diversion that occurs while at the same time ensuring that folks who need opioids or other controlled substance can get them." Ashley Dep. at 234:2-8, Ex. B.

There is, necessarily, a tradeoff between these goals. If Congress cared only about preventing diversion, it could prohibit the distribution of opioids entirely. If Congress cared only about ensuring that the American public had access to medications, then it could eliminate any restrictions on distribution (including the CSA's restrictions on registration of distributors). But Congress pursued neither goal at all costs. Instead, DEA must—following Congress's directive in the CSA—balance the risk of diversion against the risk that necessary medications will be unavailable. Decreasing one risk necessarily increases the other.

II. Plaintiff's Suit Against Distributors Interferes with the Purposes and Objectives of the Controlled Substances Act.

State law—including tort liability under state common law—is preempted when it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona*, 567 U.S. at 399–400 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).[2] "What is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." *Id.* (quoting *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000)). Courts must consider whether the application of state tort law would skew the balance sought by the federal statutory scheme. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).

Plaintiffs' claims against Pharmacy and Distributor Defendants would stand as an obstacle to the accomplishment of the full purposes and objectives of Congress in enacting the CSA and of DEA in regulating under it. Imposing liability under state law would interfere with DEA's ability

[2] The CSA's preemption clause does not compel a contrary conclusion. A preemption clause in a statutory scheme "does not bar the ordinary workings of conflict pre-emption principles." *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869 (2000). The CSA's preemption clause only disavows any intent by Congress to occupy the field but expressly calls for application of ordinary conflict preemption principles. 21 U.S.C. § 903; *see also Geier*, 529 U.S. at 873-74 ("The Court has thus refused to read general 'saving' provisions to tolerate actual conflict both in cases involving impossibility and in 'frustration-of-purpose' cases." (internal citations omitted)).

to regulate under and to enforce the CSA in accordance with the risks and benefits of the distribution of opioids as Congress mandated.

In essence, Plaintiffs assert that Pharmacy and Distributor Defendants should have limited the supply of opioids, by identifying and refusing to ship allegedly suspicious orders. Plaintiffs focus only on the alleged harms from opioids and the alleged risks of diversion—they ignore that Congress imposed on DEA an "obligation to ensure that there is no interference with the dispensing of controlled substances to the American public in accordance with the sound judgment of their physicians." Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,719-20 (Sept. 6, 2006).

The potential for a conflict between these goals is not speculative. Even according to a DEA official testifying before Congress, "the overwhelming majority of prescribing done by physicians in America is conducted responsibly" and that "99.5 percent of the prescribers . . . are not overprescribing." Prevoznik Dep. Ex. 14 at 2, Ex. C. But Plaintiffs' expert James Rafalski's report asserts that upwards of approximately 90% of the doses delivered by AmerisourceBergen, Cardinal, McKesson, CVS and Walgreens were "suspicious orders that should not [have been] shipped." Rafalski Rep. at 41, Ex. D. If, as Plaintiffs contend, the volume of distributed opioids should have been reduced by 90%, then prescriptions ordered by the majority of responsible physicians (the 99.5%) necessarily would have gone unfilled.

The effect of Plaintiffs' claims resembles the effect of the fraud-on-the-FDA claims that the Supreme Court held preempted in *Buckman*. 531 U.S at 343. Both the FDA and DEA were charged with regulating distribution (the FDA of medical devices and DEA of opioids) without interfering with decisions "committed to the discretion of health care professionals." *Id.* at 350. The Supreme Court explained that permitting liability under state tort law for fraud on the FDA

would "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* Similarly, here, state tort liability for improper distribution of opioids would inevitably conflict with the statutory framework enacted by Congress and with DEA's responsibility to regulate under and enforce that framework. Because DEA's authority—like that of the FDA—is used "to achieve a somewhat delicate balance of statutory objections," imposing state tort liability would upset this balance and thus interfere with the federal scheme. *Id.* at 348.

As in *Geier v. Am. Honda Motor Co.*, Plaintiffs' simplistic approach to liability is inconsistent with the balanced approach of the regulatory and statutory scheme. There, plaintiffs attempted to impose liability for failing to include airbags. In plaintiffs' view, "the more airbags, and the sooner, the better." 529 U.S. at 874. But this was not the approach of the Department of Transportation, which preferred "a mix of different devices introduced gradually over time" that would "lower costs, overcome technical safety problems, encourage technological development, and win widespread consumer acceptance." *Id.* at 874-75. Here, Plaintiffs' liability theories—premised on the view that "the fewer [opioids], and the sooner, the better"—are inconsistent with DEA's obligation under the CSA "to ensure that there is no interference with the dispensing of controlled substances to the American public in accordance with the sound judgment of their physicians." Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,719-20 (Sept. 6, 2006).

Plaintiffs cannot plausibly assert that their claims merely seek to enforce the CSA. In their motion to dismiss, Pharmacy and Distributor Defendants denied that any duty arose under the CSA but, in the alternative, argued that any duty alleged by Plaintiffs under the CSA would be owed to DEA rather than Plaintiffs. In addressing these arguments, this Court stated that "[t]he duty that

Plaintiffs allege is not so narrow." Doc. 1025, at 78. To the extent that Plaintiffs seek to impose liability on Pharmacy and Distributor Defendants for distributing opioids in compliance with the CSA, their claims would unquestionably interfere with DEA's duty to ensure the availability of opioids.

Even if Plaintiffs sought to employ state law to impose penalties only for actions that they claim are prohibited by federal regulations, imposing a greater remedy than DEA chooses to impose creates a conflict: "[I]t does not follow that the state and federal authorities may supplement each other . . . . The conflict lies in remedies, not rights. . . . [W]hen two separate remedies are brought to bear on the same activity, a conflict is imminent." *Garner v. Teamsters, Chauffeurs & Helpers Local Union No. 776*, 346 U.S. 485, 498–99 (1953). That is, state law may neither "curtai[l]" nor "exten[d]" federal law. *Id.* at 501. And according to its plain terms, "the [CSA] is a statute enforceable only by the Attorney General and, by delegation, the Department of Justice." *Schneller v. Crozer Chester Med. Ctr.*, 387 F. App'x 289, 293 (3d Cir. 2010). When a state law tort claim "is strictly about [a defendant's] compliance with federal regulations that are enforceable only by the Federal Government," the claim is preempted. *McDaniel v. Upsher-Smith Labs.*, 893 F.3d 941, 944-45 (6th Cir. 2018).

If Plaintiffs' claims were viable, fear of imposition of state tort liability would burden DEA with additional, unnecessary reports. This is precisely the danger recognized in *Buckman*: State tort liability would "cause [CSA registrants] to fear that their disclosures to [DEA], although deemed appropriate by the Administration, will later be judged insufficient in state court." 531 U.S. at 351. "[Registrants] would then have an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on [DEA]." *Id.*

The imposition of state tort liability would prevent DEA from fulfilling its mandate—in regulating under and enforcing the CSA—to implement the balance between the risk of diversion and the need to ensure that the American people have access to necessary drugs. Because Plaintiffs' claims would interfere with the accomplishment of the full purposes and objectives of Congress in enacting the Controlled Substances Act, they are preempted by federal law.

Dated: June 28, 2019

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